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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,688	07/27/2006	Charalabos Pothoulakis	1440.2034-003	2207

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
04/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,688	POTHOULAKIS ET AL.	
	Examiner	Art Unit	
	ROBERT LANDSMAN	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-13 and 18-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Lack of Unity

A. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 and 3-13, drawn to a method of inhibiting an inflammatory response in a tissue by administering a ghrelin antagonist.

Group II, claims 18 and 19, drawn to a method of treating inflammation by administering an agent that inhibits ghrelin activity.

Group III, claims 20-24, as drawn to a method of identifying ghrelin antagonists.

Group IV, claims 20-24, as drawn to a method of identifying ghrelin receptor antagonists.

The inventions listed as Groups I-IV do not meet the requirements for Unity of Invention or the following reasons:

Groups I-IV are drawn to methods different in design and performance, and which do not share the same or a corresponding special technical feature which define the contribution of each invention. The methods of Groups I-IV do not share a corresponding special technical feature because the methods are practiced with materially different process steps for materially different purposes and each method requires different starting materials, process steps and goals. Since these special technical features are not shared by each process, and since the common features do not establish an advance over the prior art, the inventions of Groups I-IV do not form a single inventive concept within the meaning of Rule 13.2.

The technical feature of Group I reads on an in vitro method. The technical feature of Group II is an in vivo method of treating. The technical feature of Group III is a method of identifying ghrelin antagonists. The technical feature of Group IV is a method of identifying ghrelin receptor antagonists.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Goup I is anticipated by Nakazato et al. (Nature 409, 2001) who teach that the central administration of a ghrelin antibody inhibits appetite. The administered antibody of Nakazato would inherently inhibit an inflammatory response in a tissue since the antibody would inhibit the signaling activity of the ghrelin receptor as required by instant claim 1. Therefore, Group I lacks novelty or inventive step and does not make a contribution over the prior art.

B. **Furthermore, in order to be fully responsive, in addition to electing a Group, Applicants must further elect one of the following –**

1. **Group I or II –** an agent selected from claim 4 or 19. These agents can be broken into 2 major categories – (1) those related to ghrelin itself and (2) those related to the ghrelin receptor.

However, the claims are unclear. It would be expected that the ghrelin antibody, ghrelin derivative, ghrelin receptor peptide, ghrelin analog, ghrelin receptor peptide, etc. should all be antagonists. However, "derivatives," "peptides" and "analogs" are being read as agonists until clarification is provided. It would be expected that all the agents of claim 4 would be antagonists. However, if that were the case, it is unclear as to why the *general* terms "antagonist" and "inhibitor" are included along with these more *specific* agents as opposed to being a separate claim from where claim 4 can then recite "...wherein the antagonist is an antibody, derivative, analog...".

For purposes of this restriction, Applicants must elect from Group I either (1) a ghrelin antagonist or inhibitor which is an antibody, (2) a ghrelin derivative, (3) a ghrelin receptor peptide fragment, (4) a ghrelin receptor antagonists which is an antibody, (5) a ghrelin analog, (6) a ghrelin receptor peptide, or (7) a non-peptide ghrelin antagonist.

Applicants are urged to explain whether or not "derivatives," "peptides" and "analogs" are limited to antagonists. If this is the case, then the terms "antagonist" as recited in claim 4 will be included with whichever specific antagonist is elected. It is noted that, regardless, "antibodies," "derivatives," "analogs," peptides" and "non-peptides" are still considered independent or distinct for the purposes of this restriction. The major issue is whether or not the terms "antagonist" will be recombined with the specifically elected agent. The term "antagonist" will automatically be combined if an antibody is elected.

Otherwise, it will only be combined upon explanation. Applicants are also urged to explain the difference between an "antagonist" and an "inhibitor" so any combining of these terms can be considered.

2. **Furthermore, Group I contains claims directed to more than one species of the generic invention**. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In Group I, claim 13 recites 8 different inflammatory diseases.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

C. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17 (h).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647